James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202
Telephone: 602.382.6000
Facsimile: 602.382.6070
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
Taylor Tapley Daly (admitted *pro hac vice*)
Georgia Bar No. 697887
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
Telephone: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF SUZANNE PARISIAN, M.D.

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

INTRODUCTION

Faced with the weight of authority Bard cited, and in light of the numerous examples of Dr. Parisian's improper opinions in this case, Plaintiffs ultimately acquiesce to the majority of Bard's arguments. As a result, Plaintiffs concede that Dr. Parisian:

- "will follow the limitations on her testimony imposed by the plethora of other courts" that have addressed her opinions. (Pl. Br. at 12.)
- "is not an engineer…. Plaintiffs thus concede that, to the extent that any opinion offered by Dr. Parisian at trial could be reasonably construed as being an opinion only on 'design' or 'causation' that Dr. Parisian will not offer such testimony." (*Id*. at 14.)
- "is not a medical specialist in areas relevant to causation in this case, such as an interventional radiologist, cardiologist, internal medicine doctor, or hematologist." (*Id*. at 12.)
- "cannot testify as to alternative design or design defects in Bard's IVC filters." (*Id*.)
- "is not being proffered to testify in a narrative form." (*Id*.)
- "will not express any opinions on Bard's intent, motives, or state of mind." (*Id*.)

The opposition makes clear, however, that Plaintiffs intend to circumvent their own concessions if they can. For example, although Plaintiffs admit that "Dr. Parisian cannot testify about what Bard 'intended' and will not offer any such testimony at trial," (Pl. Br. at 19, FN 10), they argue on the same page that "Dr. Parisian's opinions about what … *other entities* … intended" are entirely proper. *Id.* (emphasis added) Plaintiffs cannot have it both ways. The Court should hold Plaintiffs to their word and exclude the improper opinions identified above they conceded Dr. Parisian would not offer.

Moreover, against the holding of nearly every case that has considered the admissibility of Dr. Parisian's testimony, Plaintiffs dig in and argue she should be permitted to offer legal opinions. "The principle that legal opinion evidence concerning

the law is inadmissible is so well-established that it is often deemed a basic premise or assumption of evidence law—a kind of axiomatic principle." *Pinal Creek Grp. v. Newmont Mining Corp.*, 352 F. Supp. 2d 1037, 1042 (D. Ariz. 2005) (internal quotation omitted). Moreover, in the context of the FDA, these legal conclusions are also preempted. Indeed, Plaintiffs repeatedly conceded that Dr. Kessler, another of their regulatory witnesses, would not offer such opinions. (Dkt. No. 7805 at pp. 7-8.) Dr. Parisian should be precluded from offering legal opinions as well.

Finally, the Court should exclude Dr. Parisian's opinions because she did not employ a reliable methodology because she makes no attempt to connect her opinions with any meaningful regulatory analysis.[1]

COURT OPINIONS ADDRESSING DR. PARISIAN

Plaintiffs state that Dr. Parisian "will follow the limitations on her testimony imposed by the plethora of other courts" that have considered her testimony. (Pl. Br. At 12.) While it goes without saying that Dr. Parisian must follow the limitations *this Court* imposes, the weight of authority excluding Dr. Parisian's opinions is instructive. There is no dispute that virtually every Court exercising its gatekeeping function has excluded Dr. Parisians opinions in part, if not in full. Indeed, of the scores of opinions addressing Dr. Parisian's testimony, Plaintiffs identified only one that permitted her opinions without limitation. By contrast, at least ten courts, including two decisions from this jurisdiction, excluded Dr. Parisian's opinions in full. It's no surprise Plaintiffs disregard these decisions, disingenuously describing them as a "handful" of older cases, notwithstanding a 2015 order from a case in this litigation excluding Dr. Parisian's opinions. See *Lopez v. I-Flow Inc.*, No. CV 08–1063–PHX–SRB, 2011 WL 1897548, at *9-10 (D. Ariz. Jan. 26, 2011); *Miller v. Stryker Instruments*, No. CV 09–813–PHX–SRB, 2012 WL 1718825, at

[1] Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable Arguments In Opposition To Bard's Motions To Exclude Plaintiffs' Experts Under Rule 702 And *Daubert* (Doc. 7799). Plaintiffs' Omnibus Statement is not directed at any specific *Daubert* motion Bard filed. As such, Bard does not respond to the Omnibus Statement but instead will address any necessary issues in the context of its individual *Daubert* replies.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

*10-12 (D. Ariz. Mar. 29, 2012); Mot. Ex. C, *Robles v. C. R. Bard, Inc.*, Civil Action No. 5:13-CV-250, United States District Court for the Northern District of Texas. Rather, Plaintiffs rely on other cases that have, only in part, admitted Dr. Parisian's testimony, and claim that these cases better reflect Dr. Parisian's opinions here. Critically, however, Plaintiffs do *not* compare Dr. Parisian's opinions in those cases with her opinions in *this* case. Even in *Phillips v. C.R. Bard, Inc.*, 3:12-CV-00344-RCJ, 2014 WL 7177256 (D. Nev. Dec. 16, 2014), a Recovery Filter case, Dr. Parisian offered a totally different expert report than she does in this case (180 pages shorter, different "summary of opinions," and addressed only the Recovery).[2] Indeed, the case law Plaintiffs offer actually *supports* Bard's arguments because it excludes the categories of Dr. Parisian's testimony Bard identified in its underlying motion. A chart comparing the case law Plaintiffs cited with the categories of testimony they excluded is attached as Exhibit A. Tellingly, Plaintiffs only address *three* of the numerous examples of Dr. Parisian's specific opinions in Bard's motion. This is because a closer inspection reveals that Dr. Parisian is offering precisely the same types of opinions that other courts have excluded.

I. ARGUMENT AND CITATION OF AUTHORITY

A. Plaintiffs Concede Dr. Parisian Will Not Testify About IVC Filter Design, Testing, and Causation.

Plaintiffs concede that design and causation are "obviously outside Dr. Parisian's area of expertise" because she has no engineering experience, and no medical experience relevant to IVC filters. (Pl. Br. at 14-15.) Plaintiffs attempt to circumvent this concession, however, arguing that "none of Dr. Parisian's seven primary opinions in this case remotely touch on design or causation issues." Yet Plaintiffs ignore the specific examples from Bard's motion and the hundreds of additional pages of opinions in Dr. Parisian's report beyond her seven "primary" opinions. Plaintiffs even contradict themselves in their own brief. (*See* Pl. Br. at 17-18 (arguing that "Bard's violations of FDA regulations as

[2] In contrast, Dr. Parisian's testimony from her *Phillips* deposition is a reliable indicator of the types of impermissible testimony she will attempt to offer here.

described by Dr. Parisian are merely evidence…that its IVC filters were defectively designed").) Dr. Parisian's report and deposition are filled with these design and causation opinions, and also contain what other courts have excluded as "regulatory causation" opinions (i.e., if Bard had disclosed X to the FDA, the FDA would not have cleared the 510(k) application, or would have changed the IFU or recalled the product because of a "causal association" between X and patient injury).[3] *See e.g.*, June 21, 2017, Deposition of Suzanne Parisian ("Parisian Dep."), at 80:12 – 81:16 (testifying that Bard should have updated its IFU "based on the design of the device and what they were seeing in terms of the – the fracture of metal, the perforation, the risks that they were seeing internally, the difference between the Simon Nitinol filter and the recovery filter, that a reasonable manufacturer would have tried to have provided some guidance as to removal.").

Plaintiffs separately maintain that Dr. Parisian can testify regarding the adequacy of Bard's IVC filter testing, and "the notice [testing or literature] provide[s] to medical device manufacturers about potential problems with their products." (Pl. Br. 15.) Plaintiffs simply assert that because Dr. Parisian reviewed product testing at FDA, she can opine on the adequacy of testing and whether that testing provided "notice" to manufacturers for any marketed drug or device. This is not the case, as even the authority Plaintiffs rely on recognizes. *See e.g.*, *Jones v. Novartis Pharm. Corp.*, 235 F. Supp. 3d 1244, 1260 (N.D. Ala. 2017) ("Dr. Parisian will not be permitted to testify to 'notice' as a method of circumventing the court's ruling preventing her from discussing causation…Dr. Parisian is a regulatory expert, yet in her report she opines that certain drug potencies, a study on match factory workers in the 19th century, and causal associations between other [biophasphate] drugs and femur fractures should all have put Novartis on 'notice.' Dr.

[3] *See e.g.*, *Georges v. Novartis Pharm. Corp.*, 2012 WL 9064768 at *10 (C.D. Cal. Nov. 2, 2012) (excluding testimony and citing other Novartis cases that have done the same); *Guenther v. Novartis Pharm. Corp.*, 6:08-CV-456-ORL-31, 2013 WL 1278089 (M.D. Fla. Mar. 28, 2013) (recognizing "that to opine as to whether the label should have been revised, Parisian would need to discuss whether there was a causal association between Zometa and ONJ, which is essentially the same as discussing whether there was a causal relationship between Zometa and ONJ").

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Parisian is not an expert on bisphosphonate medications, a toxicologist, or a pharmacologist, and she will not be permitted to opine that Novartis should have conducted safety evaluations more quickly or should have noticed a link between bisphosphonates and femur fractures earlier."). *Compare with* (Ex. B, Parisian Dep., at 103:7 – 105:8 (opining that "Bard's performance of Meridian corrosion testing is flawed and raises significant questions about filter durability and safety" but conceding that "I'm not a person that would market myself as – as people who would be experts in that.").) As a result, Dr. Parisian's design, testing, and causation opinions should be excluded.

B. The Court Should Exclude Dr. Parisian's Narrative Testimony.

Plaintiffs concede that Dr. Parisian cannot offer narrative testimony, but a few pages later, argue that her narrative is necessary to support her opinions. (Pl. Br. at 12; 14.) Plaintiffs, however, confuse the issue of narrative testimony. The problem is not the volume of documents on which Dr. Parisian relies. Rather, Dr. Parisian's total lack of regulatory analysis renders her testimony inadmissible because it is unhelpful to the jury.[4] Dr. Parisian makes no attempt to connect what amounts to a closing argument better heard from counsel to any FDA regulations. For example, on page 160 of her report, Dr. Parisian cites applicable regulations for her opinion that "Bard developed its 'next generation' of IVC filters based on piecemeal reactive modifications to its flawed original RNF filter platform rather than use quality science and medical device design principles," which contains sub-opinions including that "Bard's evolution of changes starting with the RNF were not primarily made to improve quality, safety, and efficacy or to protect patients but rather primarily to address sales force and physician perceptions about device problems and help keep and expand market share." Dr. Parisian cites the following regulations and statute:

- 21 CFR § 820.198 – outlining complaint file requirements;

[4] Regarding Plaintiffs' contention that Dr. Parisian is not an advocate, Bard will let Dr. Parisian's deposition testimony and expert reports speak for themselves as to whether her advocacy renders her opinions unreliable or unhelpful.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

- 21 CFR § 820.30 – establishing and maintaining design controls "to ensure that specified design requirements are met";
- 21 CFR § 820.100 – requiring manufacturers to "establish and maintain procedures for implementing corrective and preventative action";
- 21 CFR § 820.75 – requiring manufacturers to establish and maintain processes for validating manufacturing procedures;
- 21 CFR § 820.250 – requiring manufacturers to establish "valid statistical techniques";
- 21 USC § 352(a)(f)(1)(2) – defining that a "drug or device shall be deemed to be misbranded" for a "false or misleading label."

Dr. Parisian makes no attempt to connect any of these generic regulations with her specific opinion, or how the voluminous Bard documents that supposedly support her opinion relate to any analysis under these regulations. This "analytical gap" exemplifies why courts regularly exclude Dr. Parisian's opinions because there is no useful expert analysis. *See e.g.*, *Lopez*, 2011 WL 1897548, at *10 ("Dr. Parisian's report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation…This deficiency has also been noted by other courts in excluding such testimony from Dr. Parisian.") (*citing Gen.Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.")). Dr. Parisian's narrative testimony, devoid of regulatory analysis, should be excluded.

C. The Court Should Exclude Dr. Parisian's Statutory and Regulatory Compliance Opinions Because They Are Legal Conclusions and Preempted.

It is universally accepted that expert witnesses cannot give legal opinions. *See Pinal Creek*, 352 F. Supp. 2d at 1042. Plaintiffs repeatedly conceded that Dr. Kessler, another of their regulatory witnesses, would not offer such opinions. (Dkt. No. 7805 at

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

pp. 7-8.) Here, however, Plaintiffs double down, maintaining that Dr. Parisian can offer legal conclusions because they do not reach an "ultimate issue." (Pl. Br. at 17-18) Even assuming that Plaintiffs' argument is correct, Plaintiffs do not address *any* of the specific examples in Bard's motion, or explain how those opinions, such as concluding that Bard "failed to adequately warn physicians, patients, and its own sales force of the risks," and that Bard's post-market procedures were "flawed, helped underestimate patient risk, and permitted continued commercial release of misbranded and dangerous products," do not embrace ultimate issues. (Mot. at 3-4.) Plaintiffs cite a few opinions that, without citing any legal authority, distinguish violating FDA statutes and regulations from other legal conclusions. Plaintiffs, however, cannot overcome the overwhelming weight of authority that an expert cannot provide legal conclusions, including violating FDA regulations. (*Compare, e.g.* Ex. A (including cases cited by Plaintiffs prohibiting legal conclusions) *with* June 13, 2014, Deposition of Suzanne Parisian, attached as Exhibit C, at 123:16-23 ("It's your opinion that the Recovery filter was adulterated and misbranded?" "Yeah. It didn't perform as cleared. It was cleared as a permanent filter, and it did not perform as a – it didn't perform like the SNF or any other permanent filter. So that makes it adulterated right there."); 206:7-9 ("[I]t's a prohibited act to sell a product that's adulterated and misbranded."); 244:2-7 ("[Bard] can't do that. That's not allowed in terms of the requirements. It's a prohibited act to sell a device that's not safe and effective and adequately labeled. You are not adequately informing the physician about this device before he implants it in a patient.").)

Plaintiffs gloss over Bard's preemption argument, including the fact that FDA never removed any of Bard's IVC filters from the market, and never found that Bard violated any FDA regulations. In other words, Dr. Parisian speculates that if Bard had disclosed certain information manufacturers *never* customarily submit to FDA, such as internal emails and memoranda, draft testing documents, draft PowerPoint presentations, and other documents that the FDA would not ordinarily review or rely on, then FDA would have taken certain actions or that Bard would have been required to stop selling its

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

IVC filters. The United States Supreme Court squarely rejected this reasoning and held it preempted. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477, 186 L. Ed. 2d 607 (2013) ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.') (internal quotation omitted). Plaintiffs argue that this is permitted because they are not alleging a stand-alone fraud on the FDA claim, but fail to explain why using the exact same "fraud on the FDA" evidence somehow exempts them from *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341 (2001).[5]

Plaintiffs rely on two cases to claim that this second-guessing the FDA is permissible, *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287 (S.D. Ill. Dec. 16, 2011) and *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565 (E.D. La. 2005), but both were decided before *Bartlett*. (Pl. Br. 22-23.) More generally, Plaintiffs cite *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D.W. Va. 2013), which was also decided before *Bartlett*, and only stated that "Dr. Kessler may testify, for example, that Bard did not disclose certain information to the FDA that Dr. Kessler, as a former Commissioner of the FDA, would have found *pertinent*." (emphasis added). Dr. Kessler opining that he would have wanted to know "X", versus Dr. Kessler opining that Bard violated FDA regulations because the FDA was never told "X", are two very different opinions. The court recognized this in concluding that "Dr. Kessler may not testify that Bard violated FDA regulations—such testimony would be drawing legal conclusions." *Id*. at 629 (excluding opinions such as "Bard *failed to adequately disclose* adverse risks associated with their products," "Bard *failed to warn* on its label," and prohibiting Dr. Kessler from using any terms that "have a separate,

[5] Plaintiffs also incorporate by reference their response to Bard's preemption argument in its Motion to Exclude Dr. David Kessler. To the extent that this is permitted, Bard incorporates its reply brief related to that motion.

distinct, and specialized meaning in the law.") (emphasis original). The same goes for Dr. Parisian.

Furthermore, Plaintiffs fail to address the inherently speculative nature of second-guessing the FDA. The weight of authority clearly rejects opinions second-guessing the FDA as preempted or speculative, because "[u]nder Plaintiffs' reasoning, a plaintiff could *always* cite to a particular piece of data, presumably unconsidered by the FDA, and overcome conflict preemption." *In re Incretin-Based Therapies Prod. Liab. Litig.*, 142 F. Supp. 3d 1108, 1130–31 (S.D. Cal. 2015) ("Thus, although Plaintiffs reframe this data as new safety information, the Court declines to consider it as undermining the FDA's conclusion…the Court notes that it remains unclear whether the FDA considered this information, and if it did not, whether this data would have altered the FDA's conclusion. The parties' experts dispute whether the information was material to the FDA's analysis and offer little clarity on this point. However, as noted at the hearing on these motions, it is unlikely that a conflict preemption proponent, or a plaintiff opposing the defense, would ever know the full extent of what the FDA reviewed in evaluating a safety signal….A reevaluation of scientific data or a judicial challenge to the accuracy of the FDA's conclusions would disrupt the 'delicate balance of statutory objectives' the *Buckman* Court sought to preserve.") (emphasis added).

As a result, this Court should exclude such speculative and preempted testimony as numerous other courts have done. *See e.g.*, *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 767–68 (S.D. Ohio), *aff'd*, 680 F. App'x 369 (6th Cir. 2017) ("Plaintiffs' argument that Abbott withheld certain information or misrepresented the results of studies in its 2005 and 2007 submissions to the FDA appears to be a fraud-on-the-FDA theory, which is preempted…Regardless, an expert's opinion that the FDA would have reacted differently if the submissions to the FDA in 2005 and 2007 had been supported by different evidence is speculative.") (citations omitted); *In re Trasylol Products Liab. Litig.*, No. 08-MD-01928, 2010 WL 4259332, *12 (S.D.Fla. Oct. 21, 2010) ("[An expert] may not speculate as to what the FDA would have done in hypothetical circumstances.");

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Webster v. Pacesetter, Inc., 259 F.Supp.2d 27, 37 (D.D.C. 2003) ("Nor can plaintiffs create an issue of fact regarding their defective warning claim by speculating that if the FDA had known of the delayed perforation and tamponade incidents during the clinical trials and *if* defendant had investigated all the adverse incidents, the FDA would have either recalled the [product] or placed it on alert." (emphasis in original)).

D. Plaintiffs Concede that Dr. Parisian Cannot Opine on Corporate Intent or Ethics.

Much like Plaintiffs contradictory arguments about Dr. Parisian's legal conclusions, Plaintiffs first concede that Dr. Parisian cannot testify about Bard's intent, but then claim that Dr. Parisian can opine about "what Bard knew internally," "why the FDA took the actions it did," and "what the intent of the SIR Guidelines are" because she "relies on the record." (Pl. Br. at 19.) Courts preclude experts from opining about intent because witnesses are not mind readers. If Dr. Parisian, as Plaintiffs concede, cannot opine about Bard's intent, she cannot opine about *anyone's* intent. Plaintiffs also fail to address any of the deposition testimony Bard cited regarding Dr. Parisian's speculation as to what Bard knew at certain times. Plaintiffs provide no legal authority for their position that an expert can speculate as to third parties' state of mind, or that Dr. Parisian's speculation as to what Bard "knew" at certain times is different than any other "state of mind" testimony. Regardless of Dr. Parisian's particular phrasing, numerous courts have excluded identical state of mind opinions. *See e.g.*, *Johnson v. Wyeth*, 2012 WL 1204081 (D. Ariz. Apr. 11, 2012) ("Dr. Parisian…may not offer opinions concerning defendants' motive, intent, knowledge, or other state of mind," including examples such as "[i]nternal Wyeth documents demonstrate that the company did not intend…"); *Jones,* 235 F. Supp. 3d at 1264 ("Dr. Parisian has no specialized knowledge or scientific/medical expertise that provides her with a superior ability to judge Novartis's knowledge, and there is no basis for finding that the jury needs her assistance in evaluating Novartis's knowledge" and excluding opinions such as "Novartis chose not to accurately update its sales force or prescribers about the growing risk of association.").

As a result, all of Dr. Parisian's state of mind opinions, regarding Bard's or third parties' knowledge, intent, or other state of mind, should be excluded. *Pritchett v. I-Flow Corp.*, No. 09-CV-02433-WJM-KLM, 2012 WL 1059948, at *6 (D. Colo. Mar. 28, 2012) ("Obviously, [Dr. Parisian] therefore has no direct knowledge of I–Flow's state of mind or intent regarding development, use, marketing or promotion of the pain pump. Her written opinion is riddled with conclusory statements about I–Flow's purported knowledge and intent based on her review of documents or circumstances related to the FDA process.").

E. Dr. Parisian's Testimony is Not Reliable Because She Does Not Employ A Reliable Methodology.

Plaintiffs argue against a straw man. Bard never argued that Dr. Parisian needed to apply the scientific method to her regulatory opinions. Instead, Bard argued that Dr. Parisian provides no meaningful link between her opinions and the regulations and statutes she cites. She does not explain *why* the documents she cites run afoul of the cited regulations, or *why* Bard was required to disclose those documents to the FDA in the first place. As discussed above in Section II(B), and as noted by other courts, Dr. Parisian's opinions suffer from a "striking disconnect" between opinions and seemingly unrelated regulations. *In re Trasylol*, 709 F. Supp. 2d at 1339 (S.D. Fla. 2010). In other words, the Court should "conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 519, 139 L. Ed. 2d 508 (1997).

CONCLUSION

Dr. Parisian's opinions are not only inadmissible under Rule 702, but are also unhelpful and unreliable under *Daubert*. Accordingly, the Dr. Parisian's opinions should be excluded in their entirety.

//

//

//

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

DATED this 18th day of October, 2017.

s/ Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
Taylor Tapley Daly
Georgia Bar No. 697887
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com
taylor.daly@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
JCondo@swlaw.com
ASheridan@swlaw.com

Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that October 18, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.
Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000